



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-0980]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "National Environmental Assessment Reporting System (NEARS)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on April 08, 2022, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Environmental Assessment Reporting System (NEARS) (OMB Control No. 0920-0980, Exp. 08/31/2022) - Revision - National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a three-year Paperwork Reduction Act (PRA) clearance for the National Environmental Assessment Reporting System (NEARS) to collect data from foodborne illness outbreak environmental assessments routinely conducted by local, state, territorial, or tribal food safety programs during outbreak investigations. Prior to the development of NEARS, environmental assessment data were not collected at the national level. The data reported through this surveillance system provides timely information on the causes of outbreaks, including environmental factors associated with outbreaks, and are essential to environmental public health regulators' efforts to respond more effectively to outbreaks and prevent future, similar outbreaks. This surveillance system was specifically designed to link to CDC's National Outbreak Reporting System (NORS) (OMB Control No. 0920-1304, Exp. 09/30/2023), a disease (e.g., enteric diseases transmitted by food) outbreak surveillance system. NEARS was developed by the Environmental Health Specialists Network (EHS-Net), a collaborative network of

CDC, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and nine state food safety programs (California, Connecticut, Georgia, Iowa, New York, Minnesota, Oregon, Rhode Island, and Tennessee). The network consists of environmental health specialists (EHSs), epidemiologists, and laboratorians.

While conducting environmental assessments during outbreak investigations is routine for food safety program officials, reporting information from the environmental assessments to CDC is not routine. Local, state, federal, territorial, and tribal food safety programs are the primary respondents for this data collection. One official from each participating program will report environmental assessment data on outbreaks. These programs are typically located in public health or agriculture agencies. In the U.S., there are approximately 3,000 such agencies.

Not every program of the approximate 3,000 programs will register for NEARS and respond every year. Currently, 34 programs have entered outbreak data into NEARS. We expect up to 10 additional programs will register to participate in NEARS over the next three years, to reach a maximum of 44 reporting programs.

It is not possible to determine exactly how many outbreaks will occur in the future, nor where they will occur. Over the past six years, we received 1,261 reports to NEARS, with the highest number of 307 reports in 2018, and a yearly average of

210 reports. Based on these reporting trends, we estimate that each participating program will report up to seven foodborne illness outbreaks per year; therefore, up to 308 outbreaks may be reported annually to NEARS for the duration of the next PRA clearance.

The activities associated with NEARS that require a burden estimate consist of registration, training, observing, data recording, and data reporting events. Food safety programs interested in participating in NEARS must first register to use the system. The anticipation of 10 new programs over the next three years is rounded to three new programs per year. Therefore, the total estimated annual burden associated with registration is one hour (10 minutes per hour x three registrations = 0.5 hours rounded to one hour).

The next activity is the training for the food safety program personnel participating in NEARS. These staff will be encouraged to attend a Microsoft Teams/Zoom Meeting (i.e., webinar) training session conducted by CDC staff. This training is voluntary and will cover identifying environmental factors, logging in and entering data into the web-based NEARS data entry system, and troubleshooting problems. Training burden is based on the maximum expected participation from the reporting entities which could be up to 10 additional local and state health departments (most current participants have already taken the training). We estimate the burden of this training to be a maximum of two hours. Respondents will only be required to take

this training one time. Assuming a maximum participation of up to 10 new programs and about five staff being trained at each participating program, the total estimated burden associated with this training is 100 hours (two hours x 10 entities x five staff per entity).

Although not a requirement, food safety program personnel participating in NEARS will also be encouraged to complete CDC's Environmental Assessment Training Series (EATS). This e-Learning course provides training to staff on how to use a systems approach in foodborne illness outbreak environmental assessments. Participants acquire in-depth skills and knowledge to investigate foodborne illness outbreaks as a member of a larger outbreak response team, identify an outbreak's environmental causes, and recommend appropriate control measures. The course is presented in the context of a simulated virtual environment where participants can interact and practice the skills being learned. We estimate the burden of this training to be a maximum of 10 hours. Respondents will only take this training one time. Assuming a maximum participation of up to 10 new programs and approximately five staff being trained at each program, the estimated burden associated with this training is 500 hours (10 hours x 10 entities x five staff per entity).

Data reporting activities for NEARS will be done once at each establishment involved in the outbreak. Information collection activities for NEARS consist of the following: NEARS data reporting and NEARS manager interview.

For each outbreak, the respondent (one official from each participating program) will spend around 30 minutes recording environmental assessment data on pen and paper. Assuming a maximum number of 308 outbreaks, the estimated annual burden is 150 hours (30 minutes per outbreak x 300 outbreaks) for recording observations.

The manager interview will be conducted on pen and paper at each establishment associated with an outbreak. The respondents for this activity are the retail food managers of the outbreak establishments. Manager interviews are a routine part of outbreak investigations; however, food safety program personnel participating in NEARS conduct a structured interview and will thus conduct their interviews slightly differently than they would if they were not participating in NEARS. For this reason, we have presented the burden for this interview separately. Most outbreaks are associated with only one establishment; however, some are associated with multiple establishments. We estimate that a maximum of four manager interviews will be conducted per outbreak ($n = 4 \times 308 = 1,232$). Each interview and data reporting will take about 20 minutes. The estimated annual burden is 411 hours (20 minutes x 1,232 manager interviews).

Entering data into the NEARS Data Reporting Form (web entry) is combined for both the environmental assessment and the manager interviews and is expected to take approximately 40 minutes, for a total of 205 burden hours (40 minutes x 308 outbreaks).

As part of this Revision information collection request (ICR), the requested changes to the NEARS Data Recording Form (paper form) include an update to the definitions for contributing factors based on national workgroup recommendations. In addition, one question was added to obtain a measure of the community's social vulnerability in the census tract where the food establishment is located. The social vulnerability index (SVI) will be added to the NEARS Data Reporting Form (web entry) as a change request in the next fiscal year. These form modifications are not anticipated to change the time burden per response.

Due to the anticipated increase in reporting sites from 34 to 44 registered food safety programs with each reporting up to seven outbreaks each year, the total estimated annual burden for this information collection is 1,371 hours. This reflects an increase in time burden of 21 hours over the previously approved 1,350 hours. The total number of respondents is 1,951 per year. This reflects an increase of 51 respondents over the previously approved 1,900 respondents. There are no costs to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Food safety program personnel	NEARS Food Safety Program Registration	3	1	10/60
	NEARS Food	50	1	2

	Safety Program Training			
	NEARS e-Learning (screenshots)	50	1	10
	NEARS Data Recording (paper form)	44	7	30/60
	NEARS Data Reporting and Manager's Interview (web entry)	44	7	40/60
Retail food personnel	NEARS Manager Interview	1,232	1	20/60

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